SHOCKWAVE MEDICAL

PulsePoint

Shockwave's Quarterly Newsletter to Keep Your Finger on the Pulse of IVL News, Trends & Evidence

Making Waves and Taking Names

2023 was off to a shockingly great start! We were thrilled to acquire Neovasc, a company with a first-of-its-kind technology to address refractory angina, and are looking forward to driving value for physicians and improving the lives of an underserved patient population. The excitement for our new peripheral product, Shockwave L^6, was electrifying and has continued to make waves across the U.S. Shockwave IVL and Coronary IVL became listed by SCAI as a potential therapy option across all U.S. cath labs regardless of surgical backup status. As always, we were further confirming the efficacy and safety of Shockwave IVL across different calcium morphologies through new publications. We highlight these topics and more in our latest PulsePoint Newsletter!

IVL MOA Tweetorial thread by Dr. Daniel Messiha

SEE THE POST

NEW IVL PUBLICATIONS

JACC

Safety and Effectiveness of Coronary Intravascular Lithotripsy for Treatment of Calcified Nodules

Dr. Ziad Ali, *et al.*

Read More >

JOURNAL OF ENDOVASCULAR THERAPY

Intravascular Lithotripsy and Drug-Coated Balloon Angioplasty for Severely Calcified Common Femoral Artery Atherosclerotic Disease

Dr. Konstantinos Stavroulakis, *et al.*

Read More >

CARDIOVASCULAR REVASCULARIZATION MEDICINE

Mid-term angiographic and intracoronary imaging results following intracoronary lithotripsy in calcified coronary artery disease: Results from two tertiary referral centres

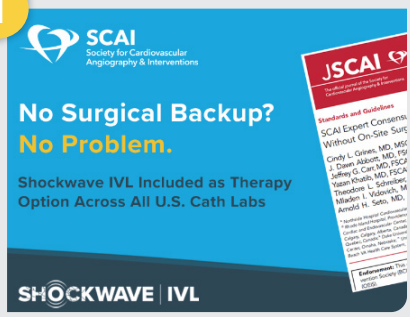
Dr. Nieves Gonzalo, *et al.*

Read More >

20 4s^2 Catalyst Calcium 40.078

Top 3 Catalyst Posts from Q1

1



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3

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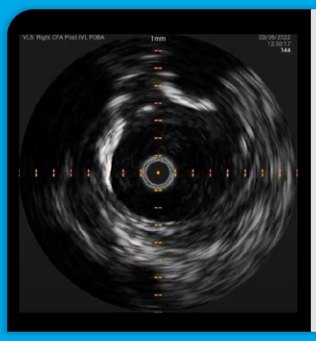
TOP 3 CONGRESS & DATA PRESENTATION HIGHLIGHTS



Vascular News Video Series

In this Vascular News Video Series, leading calcium experts discuss how to overcome the challenges of calcium with Shockwave Intravascular Lithotripsy for PAD.

Watch Now >

Achieving Success in Calcified SFA and Popliteal Lesions

Drs Carlos Guevara, Leigh Ann O'Banion and Eric Secemsky describe their experiences in treating calcified SFA & popliteal lesions using Shockwave IVL.

Read More >

Intravascular Lithotripsy for Fem-Pop Disease in the ASC

In this Backtable episode, host Dr. Aaron Fritts interviews Dr. Jim Melton and Amanda Stanley about intravascular lithotripsy in the ASC, including reimbursement trends, patient selection and the future of the device.

Read More >

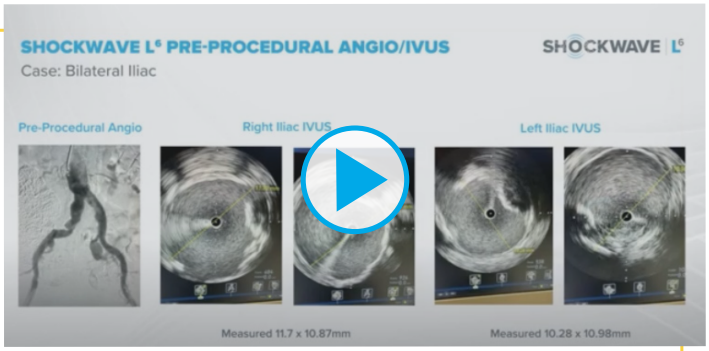
SHOCKWAVE IN THE NEWS

Shockwave Medical Announces U.S. Launch of New Peripheral IVL Catheter
Read More >

Updated SCAI Guidance Includes Coronary IVL as a Treatment Option in All U.S. Catheterization Labs Regardless of Surgical Backup Status
Read More >

Shockwave Medical Announces Agreement to Acquire Neovasc
Read More >

FEATURED VIDEO: Shockwave L⁶ in Action



Watch the Video >

UPCOMING EVENTS

NCVH
New Cardiovascular Horizons

NCVH

Check out the Shockwave symposium, "IVL's Going Big in The Big Easy".
May 31 - June 2, 2023
Register Now >

CRF® TCT
OCTOBER 23–26, 2023
MOSCONE CENTER
SAN FRANCISCO, CA

TCT

Join us at TCT, check out the Shockwave symposium and stop by the booth.
October 23 - 26, 2023
Register Now >

Important Safety Information

CORONARY ISI:

Rx only

Indications for Use—The Shockwave Intravascular Lithotripsy (IVL) System with the Shockwave C^2 Coronary IVL Catheter is indicated for lithotripsy-enabled, low-pressure balloon dilatation of severely calcified, stenotic de novo coronary arteries prior to stenting.

Contraindications—The Shockwave C^2 Coronary IVL System is contraindicated for the following: This device is not intended for stent delivery. This device is not intended for use in carotid or cerebrovascular arteries.

Warnings— Use the IVL Generator in accordance with recommended settings as stated in the Operator's Manual. The risk of a dissection or perforation is increased in severely calcified lesions undergoing percutaneous treatment, including IVL. Appropriate provisional interventions should be readily available. Balloon loss of pressure was associated with a numerical increase in dissection which was not statistically significant and was not associated with MACE. Analysis indicates calcium length is a predictor of dissection and balloon loss of pressure. IVL generates mechanical pulses which may cause atrial or ventricular capture in bradycardic patients. In patients with implantable pacemakers and defibrillators, the asynchronous capture may interact with the sensing capabilities. Monitoring of the electrocardiographic rhythm and continuous arterial pressure during IVL treatment is required. In the event of clinically significant hemodynamic effects, temporarily cease delivery of IVL therapy.

Precautions— Only to be used by physicians trained in angiography and intravascular coronary procedures. Use only the recommended balloon inflation medium. Hydrophilic coating to be wet only with normal saline or water and care must be taken with sharp objects to avoid damage to the hydrophilic coating. Appropriate anticoagulant therapy should be administered by the physician. Precaution should be taken when treating patients with previous stenting within 5mm of target lesion.

Potential adverse effects consistent with standard based cardiac interventions include– Abrupt vessel closure – Allergic reaction to contrast medium, anticoagulant and/or antithrombotic therapy-Aneurysm-Arrhythmia-Arteriovenous fistula-Bleeding complications-Cardiac tamponade or pericardial effusion-Cardiopulmonary arrest-Cerebrovascular accident (CVA)-Coronary artery/vessel occlusion, perforation, rupture or dissection-Coronary artery spasm-Death-Emboli (air, tissue, thrombus or atherosclerotic emboli)-Emergency or non-emergency coronary artery bypass surgery-Emergency or non-emergency percutaneous coronary intervention-Entry site complications-Fracture of the guide wire or failure/malfunction of any component of the device that may or may not lead to device embolism, dissection, serious injury or surgical intervention-Hematoma at the vascular access site(s)-Hemorrhage-Hypertension/Hypotension-Infection/sepsis/fever-Myocardial Infarction-Myocardial Ischemia or unstable angina-Pain-Peripheral Ischemia-Pseudoaneurysm-Renal failure/insufficiency-Restenosis of the treated coronary artery leading to revascularization-Shock/pulmonary edema-Slow flow, no reflow, or abrupt closure of coronary artery-Stroke-Thrombus-Vessel closure, abrupt-Vessel injury requiring surgical repair-Vessel dissection, perforation, rupture, or spasm.

Risks identified as related to the device and its use: Allergic/immunologic reaction to the catheter material(s) or coating-Device malfunction, failure, or balloon loss of pressure leading to device embolism, dissection, serious injury or surgical intervention-Atrial or ventricular extrasystole-Atrial or ventricular capture.

Prior to use, please reference the Instructions for Use for more information on warnings, precautions and adverse events.
https://shockwavemedical.com/IFU

Please contact your local Shockwave representative for specific country availability and refer to the Shockwave C^2 and Shockwave C^{2+} instructions for use containing important safety information.

PERIPHERAL ISI:

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Indication for Use – The Shockwave Medical Intravascular Lithotripsy (IVL) System is intended for lithotripsy-enhanced balloon dilatation of lesions, including calcified lesions, in the peripheral vasculature, including the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries. Not for use in the coronary or cerebral vasculature.

Contraindications – Do not use if unable to pass 0.014 guidewire across the lesion • Not intended for treatment of in-stent restenosis or in coronary, carotid, or cerebrovascular arteries.

Warnings – Only to be used by physicians who are familiar with interventional vascular procedures • Physicians must be trained prior to use of the device • Use the Generator in accordance with recommended settings as stated in the Operator's Manual

Precautions – Use only the recommended balloon inflation medium • Appropriate anticoagulant therapy should be administered by the physician • Decision regarding use of distal protection should be made based on physician assessment of treatment lesion morphology

Adverse Effects – Possible adverse effects consistent with standard angioplasty include: • Access site complications • Allergy to contrast or blood thinners • Arterial bypass surgery • Bleeding complications • Death • Fracture of guidewire or device • Hypertension/Hypotension • Infection/sepsis • Placement of a stent • Renal failure • Shock/pulmonary edema • Target vessel stenosis or occlusion • Vascular complications. Risks unique to the device and its use: • Allergy to catheter material(s) • Device malfunction or failure • Excess heat at target site

Prior to use, please reference the Instructions for Use for more information on indications, contraindications, warnings, precautions, and adverse events. www.shockwavemedical.com

Please contact your local Shockwave representative for specific country availability and refer to the Shockwave S^4, Shockwave M^5, Shockwave M^{5+} and Shockwave L^6 instructions for use containing important safety information.

NEOVASC REDUCER ISI:

Caution: In the United States, Reducer is an investigational device, limited by United States law to investigational use. Reducer is commercially available in certain countries outside the U.S. Please contact your local representative for specific country availability. Prior to use, please reference the Instructions for Use for more information on warnings, precautions and adverse events. https://ifu.neovasc.com